

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.
PCT/IB2003/005140

INTERNATIONAL FILING DATE
13 November 2003

PRIORITY DATE CLAIMED
15 November 2002

TITLE OF INVENTION

PHARMACEUTICAL COMPOSITIONS CONTAINING A BIGUANIDE-GLITAZONE COMBINATION

APPLICANT(S) FOR DO/EO/US

TREHAN et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

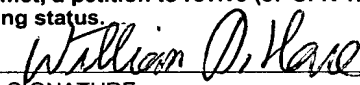
1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. **EV 483376380 US**
23. ☒ Other items or information:

Certificate of Express Mailing; Return Postcard
Copy of Notification of Missing Requirements
Information Disclosure Citation w/refs.
Petition for Extension of Time Under 37 CFR 1.136(a)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO. PCT/IB2003/005140		ATTORNEY'S DOCKET NUMBER RLL-308US	
The following fees are submitted:				CALCULATIONS	PTO USE
24. <input type="checkbox"/> Basic national fee		\$300		\$	\$0.00
25. <input type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4).		\$100		\$	\$0.00
All other situations.		\$200			
26. <input type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority		\$100			
International Search Report prepared and provided to the Office		\$400		\$	\$0.00
All other situations.		\$500			
TOTAL OF 24, 25 and 26 =				\$	\$0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0	/50 =	0	x	\$250.00
				\$	\$0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	\$130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x	\$50.00	\$
Independent claims	- 3 =	0	x	\$200.00	\$
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00				\$	\$0.00
TOTAL OF ABOVE CALCULATIONS =				\$	\$130.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	\$0.00
SUBTOTAL =				\$	\$130.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	\$0.00
TOTAL NATIONAL FEE =				\$	\$130.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$0.00
11/21/2005 MKAYPAGH 00000099 500912 10534909				TOTAL FEES ENCLOSED =	\$
01 FC:161 130.00 DA				Amount to be	\$
				Amount to be	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>50-0912</u> in the amount of <u>\$130.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0912</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO: Jayadeep R. Deshmukh, Esq. Reg. No. 34,507 Customer No. 26815</p> <p style="text-align: right;">  SIGNATURE William D. Hare NAME 44,739 REGISTRATION NUMBER </p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: TREHAN *et al.*
U.S. Application No.: 10/534,909
International Application No.: PCT/IB2003/005140
International Filing Date: 13 November 2003
Title: PHARMACEUTICAL COMPOSITIONS CONTAINING
A BIGUANIDE-GLITAZONE COMBINATION

CERTIFICATE OF EXPRESS MAILING

I hereby certify that the following correspondence:

- Transmittal Letter to the US/DO/EO Concerning a Filing Under 35 USC 371
- Executed Combined Declaration and Power of Attorney
- Copy of Notification of Missing Requirements
- Petition for Extension of Time Under 37 CFR 1.136(a)
- Transmittal of Information Disclosure Statement
- Information Disclosure Citation w/refs.
- Postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on 16 November 2005.

Michelle Morgan

Name of Person Mailing Correspondence


Signature

EV 483376380 US

"Express Mail" Mailing Label Number

EV483376380US

COPY

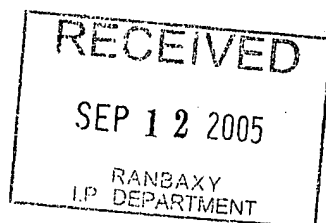


UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/534,909	Anupam Trehan	RLL-308US

26815
 RANBAXY INC.
 600 COLLEGE ROAD EAST
 SUITE 2100
 PRINCETON, NJ 08540



INTERNATIONAL APPLICATION NO.	
PCT/IB03/05140	
I.A. FILING DATE	PRIORITY DATE
11/13/2003	11/15/2002

CONFIRMATION NO. 5762
 371 FORMALITIES LETTER
 OC000000016951881
 OC000000016951881

Date Mailed: 09/08/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 05/13/2005
- Copy of the International Search Report filed on 05/13/2005
- Copy of IPE Report filed on 05/13/2005
- Preliminary Amendments filed on 05/13/2005
- Oath or Declaration filed on 05/13/2005
- U.S. Basic National Fees filed on 05/13/2005
- Priority Documents filed on 05/13/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:



- \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

WINSTON M ALVARADO

Telephone: (703) 308-9140 EXT 206

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/534,909	PCT/IB03/05140	RLL-308US

FORM PCT/DO/EO/905 (371 Formalities Notice)